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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,184	03/16/2006	Bernadette Yon-Hin	GJE-7562	2596
23557 7590 09/25/2009 SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO Box 142950 GAINESVILLE, FL 32614			EXAMINER RIPA, BRYAN D	
			ART UNIT 1795	PAPER NUMBER
			NOTIFICATION DATE 09/25/2009	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

euspto@slspatents.com

Office Action Summary	Application No. 10/572,184	Applicant(s) YON-HIN, BERNADETTE	
	Examiner BRYAN D. RIPA	Art Unit 1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7 and 8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7 and 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

In response to the amendment received on July 6, 2009:

- claims 1-5, 7 and 8 are presently pending
- in view of applicant's amendments to the claims all prior art rejections are withdrawn
- in view of applicant's amendments to the claims the previous double patenting rejection is withdrawn
- new grounds of rejection are set forth below

Claim Objections

1. Claim 7 is objected to because of the following informality. As presently written, claim 7 depends from a canceled claim 6. Since the limitation of claim 6 was incorporated into independent claim 1 by the amendments to the claims, the examiner will treat claim 7 as though it depended from independent claim 1.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 4 and 5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

More specifically, while the specification clearly provides support for the addition of the lysing agent either: (1) on the surface of the electrode or (2) in the electrode, the specification does not provide support for having the lysing agent both on the surface of the electrode and incorporated in the electrode. However, due to the amendment to the claims, as presently drafted claim 4 would require the lysing agent both on the surface of the electrode and incorporated in the electrode.

Consequently, it appears that amended claims 4 and 5 now contain new matter and appropriate correction is required.

3. Claims 1-5, 7 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

More specifically, a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

In the present instance, claim 1 recites the broad recitation "wherein the lysing agent is in or on the surface of the first electrode", and the claim also recites "wherein the lysing agent is comprised in the first electrode" which is the narrower statement of the limitation.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1-2 and 7-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Kawakami et al., “Effects of Non-Ionic Surfactants on Electrochemical Behavior of Ubiquinone and Menaquinone Incorporated in a Carbon Paste Electrode” *Bioelectrochemistry* 52, pages 51-56 (2000) (hereinafter referred to as “KAWAKAMI”) with evidence from Zierdt, “Simplified Lysed-Blood Culture Technique” *Journal of Clinical Microbiology* 23 (3), pages 452-455 (1986) (hereinafter referred to as “ZIERDT”).

Regarding claim 1, KAWAKAMI teaches a sensor comprising at least a first and a second electrode (see page 52, specifically ¶2.1 and ¶2.2 teaching the formation of the working electrode, i.e. the carbon paste electrode, as the first electrode and a platinum-wire electrode as the auxiliary electrode or second electrode) and a volume therebetween for receiving a liquid sample (see page 54 teaching the incorporation of the carbon paste electrode in a glucose biosensor which would inherently have a volume or space between the two electrodes for receiving the sample of blood) and which includes an agent that lyses cells (see page 54 teaching the carbon paste electrode having a TX layer, i.e. a lysing agent as evidenced by ZIERDT on page 452 which teaches TX or Triton X-100 being a lysing agent), wherein the lysing agent is

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comprised in the first electrode (see page 52, specifically ¶2.1 and ¶2.2 teaching TX being incorporated into a carbon comprising the first electrode).

Regarding claim 2, KAWAKAMI teaches the sensor which also comprises an enzyme of which glucose is a substrate (see page 52 teaching the use of the enzyme glucose oxidase for the detection of glucose).

Regarding claim 7, KAWAKAMI teaches the sensor wherein the first electrode comprises a carbon layer (see page 52, specifically ¶2.2 teaching the coating of glucose oxidase and graphite layer, i.e. a first carbon layer without the lysing agent), and on top thereof a carbon layer including the lysing agent (see , page 52, specifically ¶2.2 teaching the coating of the first carbon layer with a TX and graphite layer, i.e. a second carbon layer with the lysing agent).

Regarding claim 8, KAWAKAMI teaches the sensor wherein the lysing agent lyses red blood cells (see page 52 teaching the use of TX in the electrode; see also ZIERDT page 452 teaching TX lysing red blood cells).

Claim Rejections - 35 USC § 103

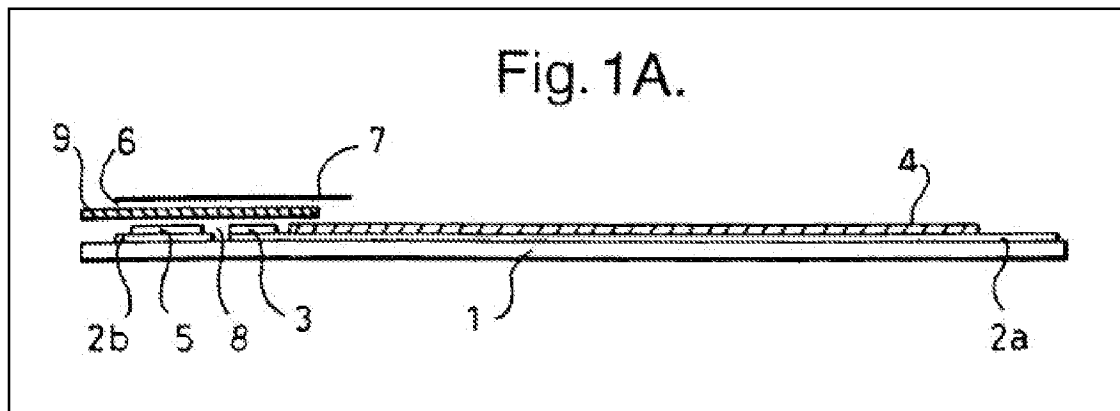
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 1 and 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over WILLIAMS in view of KAWAKAMI

Regarding claim 1, WILLIAMS teaches a sensor comprising at least a first and a second electrode (see conductive layer 2b comprising the first electrode; conductive layer 2a comprising the second electrode) and a volume there between for receiving a liquid sample (see non-conducting gap 8) and which includes an agent that lyses cells (see col. 4 lines 35–38 discussing monofilament mesh 6 being coated with a lysing agent). See figure 1a below. WILLIAMS, however, does not teach the lysing agent being comprised in the first electrode.



However, KAWAKAMI teaches a glucose biosensor where the lysing agent is comprised in the first electrode (see pages 52 and 54-55 teaching the carbon paste electrode having TX incorporated in the carbon paste electrode, i.e. a lysing agent as evidenced by ZIERDT on page 452).

Consequently, as shown by KAWAKAMI, a person of ordinary skill in the art would accordingly have recognized that the lysing agent could be incorporated in the carbon paste used to form the electrode.

Moreover, KAWAKAMI teaches that incorporating the lysing agent into the carbon paste electrode resulted in a biosensor with an improved sensor response (see page 55). As a result, one of ordinary skill in the art would have been motivated to incorporate the lysing agent into the carbon paste electrode as a way of providing for an improved sensor response.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to incorporate the lysing agent in the carbon paste electrode as claimed.

Regarding claim 3, WILLIAMS teaches the sensor also comprising a spreading layer over at least the first electrode (see monofilament mesh 6). See figure 1a above.

Regarding claim 4, WILLIAMS teaches the sensor wherein a lysing agent is comprised in a layer applied onto the first electrode (see col. 4 lines 35–40; col. 5 lines 45–51; figure 1a above).

Regarding claim 5, WILLIAMS teaches the sensor wherein an enzyme and/or a mediator are applied in one or more additional layers on the first electrode (see analyte-specific reagent 5; col. 3 lines 61–67).

Response to Arguments

Applicant's arguments, see page 4 paragraphs 1-3, filed July 6, 2009, with respect to the rejection of claim 6 under 35 U.S.C. 102(b) has been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made of amended claim 1, which now contains the limitation of previous claim 6, in view of KAWAKAMI under 35 U.S.C. 102(b) and WILLIAMS in view of KAWAKAMI under 35 U.S.C. 103(a) as outlined above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRYAN D. RIPA whose telephone number is 571-270-7875. The examiner can normally be reached on Monday to Friday, 9:00 AM to 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alexa Neckel can be reached on 571-272-1446. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Harry D Wilkins, III/
Primary Examiner, Art Unit 1795

/B. D. R./
Examiner, Art Unit 1795